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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/797,704
Filing Date: March 09, 2004
Appellant(s): AUSTIN ET AL.

Jeremy Laabs
For Appellants

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/1/2010 appealing from the Final Office action mailed 11/30/09.

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(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 17, 19-29, and 36-39 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's statement as to grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

1) The first mentioned issue as to whether US 6,111,345 is a translation of JP-111423 is not a grounds of rejection for review on appeal because US 6,111,345 was given to the Examiner by STIC for the English translation/equivalent for JP 11-111423 (Shibata).

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2) The second issue is really two part because two separate rejections were applied.

a) Whether the Examiner erred in rejecting claims 21-26 and 36-38 under 35 USC § 103 over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423)?

AND

b) Whether the Examiner erred in rejecting claims 27-29 under 35 USC § 103 over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) and further in view of Kirk Othmer (**Encyclopedia of Chemical Technology**).

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2005/0074544	PACETTI ET AL	4-2005
JP 11-111423	SHIBATA	4-1999
6,111,345	SHIBATA ET AL	8-2000
(English translation/equivalent for JP 11-111423)		
7,175,874	PACETTI ET AL	2-2007
2001/0008649	LAYROLLE ET AL	7-2001
2,842,092	POMPER	7-1958

Kirk Othmer, **Encyclopedia of Chemical Technology**, 3rd Edition, Vol. 19, "Radiation Curing", pages 607-624 (1982).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC § 103

I. Claims 22/21, 23-26 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544), hereinafter referred to as Pacetti in view of Shibata (JP 11-111423).

Pacetti provides for a system for direct coating of a cylindrically shaped object or stent (22) having a tubular portion with an outer surface, wherein the system comprises a coating material source containing a coating material comprising a solvent and a biologically active material [0063+]; a first roller member (78) having a rotatable surface; and a second roller (76) with a doctor (84) having a surface, wherein the first roller is situated relative to the coating material source so that the coating material in the coating material source can be transferred to the stent (see Fig. 10 as an example). Pacetti is silent concerning the use of an indirect coating system wherein the second coating roller is situated relative to the first coating roller to transfer coating material from the source to the first coating roller then to the second coating roller to result in coating of the stent and wherein the first roller includes a doctor blade to remove excess coating. However, it was known in the coating art, at the time the invention was made to provide for an indirect roller coating arrangement to enable a more metered coating of a cylindrically shaped object as evidenced by Shibata (See abstract and Fig. 5). Shibata sets forth a conventional indirect coating apparatus comprising a coating material source (501) containing a desired coating material; a first roller (201) having a surface; and a second roller (301) having a surface, wherein the first roller is situated relative to the coating material source so that the coating

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material in the coating material source can be transferred to the first roller surface; the first roller and second roller are situated relative to each other so that the first roller can transfer the coating material transferred to the first roller surface to the second roller surface, and the second roller is situated relative to the cylindrical member (32) so that the second roller can transfer the coating material transferred to the second roller surface to the outer surface of the cylindrical member. Shibata further provides for one or more metering mechanisms in the form of blades (500/100) for removal of excess coating material from the surface of the first roller (201) so as to control the amount of coating material applied to the cylindrical member. Thus, it would have been obvious to one of ordinary skill in the art to utilize an indirect coating arrangement as taught by Shibata in place of the Pacetti direct coating arrangement as an alternative arrangement for coating the stent to allow for a more metered supply of coating material onto the surface of the stent thereby enhancing uniformity in coating on the surface of the stent. As for the use of the doctor blade in proximity to the first roller to remove excess coating material, it would have been well within the purview of one skilled in the art to provide a doctoring blade to remove excess coating material from the first roller surface and/or even the second roller as removal of excess material would prevent application of an excess amount of coating material to the stent as well as lower manufacturing costs.

With respect to claim 21, while Pacetti does teach a grooved roller surface to facilitate transfer of the coating material [0045], Pacetti is silent concerning the use of a transfer roller arrangement wherein the surface of the second roller is grooved. However, Shibata provides the surface of the second roller (301) being grooved as illustrated in Fig. 4a/b relative to the smooth surface of the first roller (201). In light of the teachings of Shibata, it would have been obvious to

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one of ordinary skill in the art to utilize in the indirect coating apparatus as defined by the combination above, a second grooved roller in order to facilitate transfer of coating material as well as provide for a controlled amount of coating material to be applied to the stent.

With respect to claim 23, Pacetti does not suggest the surface of the second roller is rougher than the surface of the first roller. Shibata provides for the surface of the second roller (301) being rougher than the surface of the first roller (201) because the surface of the second roller has protrusions thereon as illustrated in Fig. 4a/b relative to the smooth surface of the first roller (201). The surface of the first roller contacts the surface of the second roller and the surface of the second roller contacts the outer surface of the cylindrical member (32). It would have been obvious to one of ordinary skill in the art to utilize in the indirect coating apparatus as defined by above, a second rougher roller as taught by Shibata to coat the stent with a controlled/minimal amount of coating material.

With respect to claims 25 and 26, Pacetti provides for a single metering doctor (84) but not a supplemental metering mechanism for removing excess coating material. However, Shibata provides for dual metering mechanisms in the form of two blades mechanisms (500/100) for removal of excess coating material from the surface of the first roller (201) so as to control the amount of coating material applied to the cylindrical member. Since dual metering mechanisms are known for use in removing coating from the surface of a single roller applicator, it would have been within the purview of one skilled in the art to utilize any known and conventional metering mechanisms (i.e., metering roller, air knife, etc.) and/or combinations thereto to remove excess coating from the surface of the first roller.

With respect to claims 36 and 37, see Pacetti [0067].

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II. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Pacetti (US 7,175,874).

The combined teachings of Pacetti '544 with Shibata would suggest a coating source to include a reservoir. Neither Pacetti '544 nor Shibata suggest two fluid communicating/circulating sources (i.e., two tanks or two reservoirs or main tank/sub tank) to act as a continuous supply for coating material. However, it was known in the coating art, at the time the invention was made to provide in a stent coating material supply arrangement, the provision of separate reservoirs/tanks/sources supplied/circulated to a mixing means for subsequent application to the stent so as to allow for control in concentration of ingredients used to coat the stent as evidenced by Pacetti '874 (col. 2, lines 47-52 and col. 3, lines 27-43). It would have been obvious to one of ordinary skill in the art to provide the stent coating material supply arrangement as taught by Pacetti '874 in the indirect coating apparatus as defined by the combination above in order to allow for continuous control of the concentration of ingredients supplied to form the final composition for application to the stent.

III. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544), Shibata (JP 11-111423), and Pacetti (US 7,175,874) as applied to claim 17 above and further in view of Layrolle et al (US 2001/0008649), hereinafter referred to as Layrolle.

The teachings of Pacetti '544, Shibata, and Pacetti '874 have been mentioned above but none teach or suggest one source or reservoir being a fermentor containing cells. However, it

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was known in the stent coating art at the time the invention was made, to provide for a source/reservoir to be in the form a fermentor system such as one used for culturing cells so as to be used to coat the stent as evidenced by Layrolle [0037]. In light of the teachings of Layrolle, one of ordinary skill in the art would readily appreciate the inclusion of at least one source having appropriate materials to effect a fermentor as one used in culturing cells to be used to apply such materials to the surface of the stent in the indirect coating apparatus as defined by the combination above as another option of therapeutic coating material for application to the stent. The inclusion of cells, as a part of the biological coating material, would be well within the purview of one skilled in the art because Pacetti '544 applies cellular based coating material as evidenced by [0067].

IV. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Kirk Othmer.

The teachings of Pacetti and Shibata have been mentioned above but neither teach or suggest using an energy source for converting or curing the coating material applied to the outer surface of the tubular portion in order to heat/dry the coating on the stent. However, it is well known and conventional in the coating art to use a radiation source (i.e., UV light) to cure or dry an applied coating as evidenced by Kirk Othmer (see page 616, under the heading, "Curing With Ultraviolet,..."). In light of the teachings of Kirk Othmer, one of ordinary skill in the art would readily appreciate the use of an appropriate drying source including UV light, to cure or dry an applied coating to the stent in the indirect coating apparatus as defined by the combination

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above. It would be within the purview of one skilled in the art to use an appropriate source of energy in the arrangement as defined by the combination above in accordance with the type of coating material applied to the stent.

V. Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US 2005/0074544) in view of Shibata (JP 11-111423) as applied to claim 22 above and further in view of Pomper (US 2,842,092).

The teachings of Pacetti and Shibata have been mentioned above but neither teaches or suggests at least one of the first and second rollers being adjustable to control the distance between the rollers and thereby control the thickness of coating applied to the stent. However, it is well known and conventional in the coating art to provide at least one adjustable roller (9, 33) provided in a roller pair to control the distance between the two rollers so as to control the thickness of coating supplied on a substrate or article as evidenced by Pomper (col. 3, lines 61-65). It would have been obvious to one of ordinary skill in the art to provide at least one adjustable roller provided in the roller pair (first roller or second roller) in the indirect arrangement as defined by the combination above in order to control the distance between the two rollers so as to control the thickness of coating supplied on the stent.

(10) Response to Arguments

Appellants collectively contend that if US 6111345 is not a translation of Shibata (JP 11-111423), a non-English reference, then rejections can/should only rely on teachings from the English abstract of Shibata.

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In response to this contention, the Examiner has continually relied upon Shibata (JP 11-11423), the secondary reference, for what it structurally illustrates with respect to an indirect coating apparatus which is sufficiently described in the English abstract and drawings thereto. Thus, arguments with respect to Shibata (JP 11-11423) including its English abstract will be addressed only.

Appellants impart a non-analogous art argument combined with impermissible hindsight argument together with a notion of unsupported conclusory statements to suggest that the instantly claimed invention is structurally distinguishable over the applied prior art to Pacetti (US 2005/0074544) in view of Shibata (JP 11-11423).

Acknowledgement is made of the fact that the foundation of the obviousness rejection is not to the teachings of Shibata but the teachings of Pacetti as the primary reference. Pacetti sets a foundation of coating a stent (22) using a direct roller coating arrangement wherein the coating material is transferred from a source or reservoir to the applicator roller (78) which then transfers the coating material to the stent “in close proximity to or in contact with the applicator” [0018]. Pacetti implies the transference of coating material from the source to the stent via at least one roller. Shibata, another roller coating reference which teaches transference of coating material via at least one or more rollers eventually to a cylindrical object which in this instance meters the amount of coating eventually applied to the cylindrical object sets forth an example of an indirect coating arrangement. Shibata defines analogous art because it is coating art including a coating apparatus which uses at least one roller to effect transference of coating material from a source to a cylindrical object being coated. Shibata has not been applied using impermissible hindsight. However, upon a conclusion of obviousness, it must be recognized that any judgement on

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obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392; 170 USPQ 209 (CCPQ 1971). Finally, the Examiner's conclusionary statement(s) of obviousness relating to benefit of the indirect coating arrangement of Shibata to coat the stent as oppose to the direct coating arrangement as set forth by Pacetti to allow for a more metered supply of coating material onto the surface of the stent thereby enhancing uniformity in coating on the surface of the stent is not explicitly set forth in either Pacetti or Shibata. The use of a plurality rollers in communication with each other and first being in contact with a reservoir/source of coating allows the coating material to transfer from the source to roller to roller, etc. until the coating is eventually applied on the object or article or substrate. The continued transfer of coating material from roller to roller smooths or levels the coating material and actually to some extent lessens the amount of coating eventually applied to the object or article or substrate. This aforementioned arrangement defines an indirect roller coating arrangement wherein a metered or controlled amount is applied more uniformly because excess lumps, air bubbles, etc., have been removed via the transference of coating material from roller to roller eventually to arrive at the object or article or substrate being coated. This indirect roller coating arrangement is conventional wisdom to the routineer in the coating art.

Shibata (JP 11-111423) should not be applied as argued by Appellants because it deals with an indirect coating arrangement for an object in the form of a spark plug and has nothing whatsoever to do with coating of a stent.

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This argument is well taken in that Shibata does coat a spark plug but Shibata was never applied for such a teaching because Pacetti was applied disclosing coating of the stent. Pacetti provides the foundation for using a roller coating apparatus wherein leveling the composition occurs and the coating material is applied in uniform thickness on the surface of the stent as evidenced by [0016]. Shibata does not have to show coating of the stent because that has already been established by the primary reference. Moreover, the intended use of the apparatus to coat the stent has been given no patentable weight because the stent forms no basis of the invention which is to an apparatus having structure.

Another contention Appellants relate to the withdrawal of the obviousness rejection under Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423) is that one of ordinary skill in the art would have no motivation to modify Pacetti into an indirect coating arrangement as suggested by Shibata because the Shibata coating arrangement is specifically used for coating spark plugs using a marking roller having shaped recesses with a transfer roller such that coverage gaps would result. This would cause a less desirable coated stent product to be formed so the proposed modification would be detrimental to the teachings of Pacetti.

As this argument purports that an indirect coating arrangement would be detrimental to the formation of the coated stent in Pacetti, the Examiner would suggest otherwise. Shibata provides sufficient evidence that the routineer in the art would know that another appropriately surfaced roller, whether textured/grooved or untextured/ungrooved would be positionable between the source/reservoir and the applicator roller so the coating material would be metered for eventual application to the stent. Pacetti even suggests that the applicator roller applying coating material directly to the stent would be grooved/recessed as shown in Fig. 9 to form the

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coated stent. Ergo, use in the Pacetti roller coating apparatus of another appropriately surfaced roller defining a transferring roller, positioned between the source/reservoir and the applicator roller to meter the coating applied on the stent would not be detrimental to the stent nor destroy the stent.

With respect to claim 21, Appellants argue that Shibata (JP 11-11423) in the English abstract does not suggest the second roller including grooves such that the instantly claimed limitation would be patentable over the applied prior art to Pacetti (US 2005/0074544) in view of Shibata (JP 11-11423).

As mentioned previously, Shibata illustrates so much that words are unnecessary so in Figs. 4(a) and 4(b) Shibata respectively shows the first roller (201) which is the one in communication with the source/reservoir of coating material having a smooth outer surface but the second or transfer roller (301) being textured/grooved. Since Pacetti sets forth that a textured/grooved/patterned roller would be useable in coating the stent (see Fig. 9; [0044-0045]), there is no apparent reason why in an indirect coating arrangement, one or even both of the rollers used to coat the stent would not be textured/grooved/patterned. Understandably, the routineer in the art would not put spark plug markings on a stent but the routineer in the art would know what pattern would be suitable for applying the coating to the stent to result in a useful medical product. As such, the 103 rejection of claim 21 is deemed proper under Pacetti in view of Shibata and has been sustained.

As for the obviousness rejection of claims 17 and 20 under Pacetti '544 in view of Shibata and further in view of Pacetti '874, Appellants contend that one of ordinary skill in the art would not have been motivated to further combine the teachings of Pacetti '874 to a stent

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spray coating system including two reservoirs having different coating solutions to deliver the coating material to a pressurized nozzle to be presented together with the Pacetti '544 stent roller coating system along with the spark plug roller coating system of Shibata. The Examiner should withdraw the obviousness rejection because a prima facie case of obviousness has not been set forth in combining a pressurized spray system with coating material supply with the aforementioned indirect stent roller coating combination.

It would appear in this instance that Appellants have misread the rejections with respect to claims 17 and 20 to combine all the structure of all three patents to form a defective or non-operational structure. To the contrary, the Examiner has merely established that the primary reference to Pacetti '544 shows in the embodiment of Figure 10, that a source or supply of coating material can be supplied to feeder (24; could even be pressurized as evidenced by [0032]) and then supplied to a reservoir or formed sump with respect to the applicator roller. Also, Pacetti '544 recognizes that the source or supply of coating material can be in a reservoir in the form of a tank as evidenced by the embodiment of Fig. 9. Regardless, Shibata also provides for coating material to be supplied to a reservoir in the form of a tank (501; See Fig. 5) which is then provided on the transfer roller for transfer of the coating material onto the applicator roller. Pacetti, in the later stent coating patent, US 7,175,874, further provides evidence that the routineer in the art would know with the various types of biological/medical/therapeutic materials utilized for application to the stent, that separated materials could then be supplied/circulated via separate reservoirs/tanks/sources via a mixing means for subsequent application to a feeder for application on the stent. Pacetti '874 gives attention to control in concentration of ingredients used to provide for the final composition to be coated on the stent as

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evidenced by Pacetti '874 (col. 2, lines 47-52 and col. 3, lines 27-43). In light of the various types of medical/biological/therapeutic materials utilized for application to the stent, it would have been obvious to one of ordinary skill in the art to utilize the stent coating material supply arrangement as taught by Pacetti '874 in the indirect coating apparatus as defined by the combination above, in order to allow for continuous control of the concentration of ingredients constantly supplied to form the final composition for application to the stent.

Appellants argue that the obviousness rejection of claim 20 under Pacetti '544 in view of Shibata and further in view of Pacetti '874, is flawed because it requires that coating material be circulated more than one way between the reservoir and the coating material source such as through a closed loop as required by dictionary definition.

In response to this contention, the dictionary definition of “circulate” as provided by Appellant only suggests flow as for example through the body but does not provide evidence explicitly or implicitly of two way flow. The complete listing of definitions for the term “circulate” are not even provided. Regardless, claim 20 is written in a process limiting manner and has been read as such “wherein the coating material is circulated between the reservoir and the coating material source”. The claim has been read to suggest at least flow from point A (the coating material source) to point B (the reservoir). The language is not conclusive to suggest two way flow or for a better term, recirculation. Thus, the rejection of claim 20 under Pacetti '544 in view of Shibata and further in view of Pacetti '874 has been sustained.

Claim 19 should be allowable over the teachings of Pacetti et al (US 2005/0074544), Shibata (JP 11-111423), and Pacetti (US 7,175,874) in view of view of Layrolle et al (US 2001/0008649) according to Appellants because Layrolle coats stents by depositing/growing the

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coating on the stent while the stent is immersed in a solution that includes the coating material(s). One of ordinary skill in the art would not have found it obvious to combine a fermentor containing cells as taught by Layrolle together with the indirect roller coating apparatus as defined by the combination above because there would be no reasonable expectation of success in attempting to coat a stent with coating materials taught by Layrolle applied by a roller coating machine.

This argument is not convincing to remove the obviousness rejection as applied to claim 19 because Pacetti '544, the primary reference suggests a myriad of therapeutic materials that can be used for roller application onto the stent including cells as evidenced by [0067] in the last eight lines. Therefore, use of a fermentor with cells as taught by Layrolle as a form of an active biological supply to the indirect roller applicator apparatus as defined by the combination above would be within the purview of one skilled in the art to effect a therapeutic cellular coated stent.

In Appellants' Brief immediately under the Argument section, it is contended that the Examiner erred in rejecting claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer because Shibata constitutes non-analogous art, impermissible hindsight was used in applying Shibata, and unsupported conclusionary arguments were made with respect to Shibata.

This argument is not deemed persuasive to remove the 103 rejection against claims 27-29 under Pacetti in view of Shibata and further in view of Kirk Othmer due to reasons set forth in response to these same arguments against Shibata as applied to claims 21-26 and 36-38 already set forth above. Kirk Othmer merely adds the provision of using radiative energy to cure/dry the

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coating on the stent product. Post treatment of the coated stent following application via the roller coating apparatus would be well within the purview of one skilled in the art.

Finally, Appellants argue that claim 39 is patentably distinguishable over the teachings of Pacetti in view of Shibata and further in view of Pomper because there is no motivation for one of ordinary skill in the art to make the first roller moveable to adjust a distance between the first and second rollers of the Pacetti/Shibata device proposed by the Examiner because the modification would not allow any metering to result or even coating material to be transferred.

This argument is not deemed persuasive to remove the obviousness rejection of claim 39 under Pacetti in view of Shibata and further in view of Pomper because it is well known and conventional in the coating art to provide at least one adjustable roller (9, 33) provided in a roller pair to control the distance between the two rollers so as to control the thickness of coating supplied on a substrate or article as evidenced by Pomper (col. 3, lines 61- 65). Control of the spacing between adjacent rollers in the apparatus as defined by the combination above would allow for change in thickness of coating applied. It would be common sense to the routineer in the art to maintain a desired spacing to allow the apparatus to coat via transference of coating material otherwise, the spacing of the rollers to the extent that they were fully disengaged would only serve to enable a user to clean the rollers when desired. Regardless, adjustably spaced rollers in the indirect arrangement as defined by the combination above would control coating thickness and thus control coating material supply costs.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Laura Edwards/

Conferees:

/Parviz Hassanzadeh/

Supervisory Patent Examiner, Art Unit 1716

/William Krynski/

Supervisory Patent Examiner, TC 1700